

- 103
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- c. moving at least one of the anvil and the stapling mechanism relative to the other from a closed position in which the anvil and the stapling mechanism are adjacent to one another to a tissue receiving position in which the anvil is separated from the stapling mechanism;
 - d. drawing the selected portion of tissue into a tissue receiving chamber within the operating head;
 - e. moving at least one of the anvil and the stapling mechanism relative to the other from the tissue receiving position to a stapling position in which a surrounding portion of tissue adjacent to the selected portion of tissue is clamped between the anvil and the stapling mechanism;
 - f. stapling the surrounding portion of tissue; and
 - g. resecting the selected portion of tissue from the surrounding portion of tissue.
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REMARKS

Claims 36 - 51 remain pending in this application. Claims 36, 44 and 49 have been amended to more particularly point out and distinctly claim the subject matter of the invention. In view of the above amendments and the following remarks, it is respectfully submitted that all of the presently pending claims are allowable.

The Examiner has refused to consider the IDS submitted February 19, 2002 stating that the IDS failed to comply with 37 C.F.R. 1.97 and 37 C.F.R. 1.98 which requires a legible copy of each U.S. and foreign patent submitted therewith. However, legible copies of all of the references were submitted to the patent office. A copy of the Information Disclosure Statement and the Transmittal submitted therewith indicating that copies of these references were mailed, both of which include certificates of mailing certifying that this information was forwarded to the Patent Office are submitted herewith.

The Examiner further stated that the IDS fails to comply with 37 C.F.R. 1.97 and 1.98 because

it does not include a concise explanation of the relevance of the single foreign language reference included therewith. However, MPEP § 609 states:

If an item of information in an IDS fails to comply with all the requirements of 37 C.F.R. 1.97 and 37 C.F.R. 1.98, *that item* of information in the IDS will not be considered and a line should be drawn through the citation to show that it has not been considered. *However, other items of information that do comply with all the requirements of 37 C.F.R. 1.97 and 37 C.F.R. 1.98 will be considered by the Examiner.*

M.P.E.P. § 609 III C(1)

Therefore, it is respectfully submitted that the IDS complies with 37 C.F.R. 1.97 and 1.98 as copies of all of the references were submitted on February 13, 2002 and that all of the references, with the exception of the single foreign language reference should be marked considered by the Examiner. The Examiner is invited to contact the undersigned to obtain additional copies of these references if he is unable to locate them in the Patent Office. However, as the copying and mailing fees for submitting additional copies are significant, it would be greatly appreciated if the originally mailed copies could be located.

Claims 36 - 38 and 40 - 43 stand rejected under 35 U.S.C. § 103 as obvious over Tsuruta (U.S. Patent No. 5,389,098) in view of Sauer (U.S. Patent No. 5,562,694). The Examiner stated in support of the rejection that Tsuruta shows a stapling assembly substantially as claimed except for the grasper for drawing tissue into the cutting zone. The Examiner further stated that Sauer shows a grasper as claimed and that it would have been obvious to have combined the stapling assembly of Tsuruta with the grasper of Sauer to achieve the claimed invention.

Claim 36 recites an apparatus for resecting tissue within a body lumen, comprising "an operating capsule including *a coupling structure for selectively coupling to a flexible endoscope, the operating capsule being sized so that, when in an operative position entirely located within a body lumen adjacent to a selected portion of tissue to be resected structural integrity of luminal tissue is maintained*, the operating capsule including a suturing assembly and defining a cutting zone adjacent to the suturing assembly."

In contrast, Tsuruta shows various rigid surgical instruments which are inserted into body cavities *via incisions made in body walls*. (Col. 2, lines 44-46). The Examiner has dismissed applicants arguments concerning the unsuitability of the Tsuruta devices for intra-luminal use by stating that all of the rigid devices *could* be placed entirely within a body lumen and that any device has some degree of rigidity. As noted previously, none of these devices could be placed entirely within a body lumen as they would destroy any lumen into which they were inserted. In addition, none of these devices includes an operating capsule including a coupling structure for coupling to a flexible endoscope. As flexible endoscopes are used for insertion into body cavities through natural orifices and not through surgical incisions, there is no reason to couple such a device to an endoscope. The rigidity of these devices also makes them unsuitable for use with flexible endoscopes as they are not flexible enough to avoid causing significant damage to luminal tissue if this were attempted. Furthermore, none of these devices includes an operating capsule sized so that, when in an operative position located within a body lumen structural integrity of luminal tissue is maintained.

Rather, the devices of Tsuruta include a stapling mechanism at the distal end of a rigid shaft which, when in an operative position, extends from outside the body, through an incision into a body cavity. Therefore, it is respectfully submitted that none of the Tsuruta devices includes an operating capsule as recited in claim 36.

Similarly, Sauer shows a rigid instrument which is not coupleable to a flexible endoscope and which includes no capsule which is locatable entirely within a body cavity. Although Sauer describes the device as useful in endoscopic surgical procedures, it is clear that the device is not intended for use with a flexible endoscope. Specifically, Sauer states that endoscopic procedures involve "incising through body walls for examining, viewing and/or operating on various bodily organs or structures" with a trocar being employed to create the incision and tubes being inserted through the incision and left in place in the abdominal wall so that tools may be inserted therethrough. (Col. 1, lines 17-24). Thus, the elongated body portion 14 is not sufficiently flexible for use with a flexible endoscope and includes no coupling structure for selectively coupling to a flexible endoscope. Nor would such a coupling be of any use with this device.

For these reasons, it is respectfully submitted that neither Tsuruta nor Sauer either show or suggest an apparatus for resecting tissue within a body lumen, comprising "an operating capsule including *a coupling structure for selectively coupling to a flexible endoscope*, the operating capsule being sized so that, when in an operative position entirely located within a body lumen adjacent to a selected portion of tissue to be resected structural integrity of luminal tissue is maintained, the operating capsule including a suturing assembly and defining a cutting zone adjacent to the suturing assembly," as recited in claim 36. Furthermore, both of these references are specifically directed to rigid devices for use with open surgery and therefore teach away from the a device for use with a flexible endoscope.

It is therefore respectfully submitted that claim 36 is not obvious over Tsuruta and Sauer either taken alone or in combination and that this rejection should be withdrawn. Because claims 37, 38 and 40 - 43 depend from and, therefore, include all of the limitations of claim 36, it is respectfully submitted that these claims are also allowable.

Claim 39 stands rejected under 35 U.S.C. § 103 as obvious over Tsuruta in view of Sauer as applied to claim 36 in further view of Bessler (U.S. Patent No. 5,197,649). The Examiner stated, in support of the rejection, that Tsuruta in view of Sauer show the invention as claimed with the exception of the endoscope and that Bessler shows an endoscope as claimed. However, as indicated above, Tsuruta and Sauer do not show the invention as claimed in claim 36 and Bessler fails to cure the defects noted above in regard to this rejection of claim 36.

Specifically, as discussed above in regard to claim 36, the rigid devices of Sauer and Tsuruta are for very different applications (i.e., open surgery) than the claimed device and that these differences taught away from combinations with flexible endoscopes. Clearly none of the references provides the motivation for such a combination. Specifically, the device of Bessler is intended to eliminate the type of open procedures for which the devices of Tsuruta and Sauer are designed and adding a flexible endoscope as shown to either of these devices (or a hybrid thereof) would bring back the problems that the Bessler device is attempting to address. Specifically, there is clearly no motivation in either Tsuruta

or Sauer to combine with a flexible endoscope as the flexibility and steering capabilities of such an endoscope would be useless within the rigid bodies of these devices. And the device of Bessler is an attempt to eliminate the need for incisions in performing operations such as anastomoses of the colon. Thus, combining the teaching of Bessler with any rigid device is completely contradictory to the teachings of that reference. Among the disadvantages of prior devices discussed, Bessler states that "[m]any of the available devices have a rigid structure which preclude (sic) their application for other than straight intestines." Thus, the combination of this device with a rigid structure is clearly taught away from by Bessler.

It is therefore respectfully submitted that none of the cited references provides any motivation for the combination suggested by the Examiner and that, therefore, this rejection is based on an impermissible hindsight reconstruction of the invention. For this reason and for the reasons stated above in regard to claim 36, it is respectfully submitted that claim 39 is not rendered obvious by Tsuruta, Sauer and Bessler and that this rejection should be withdrawn.

Claims 44 - 48 stand rejected under 35 U.S.C. § 103 as obvious over Tsuruta in view of Bessler. The Examiner stated, in support of the rejection that Tsuruta discloses the invention substantially as claimed except for the internal endoscope, but that Bessler shows such an endoscope. Claims 39 and 44-50 stand rejected under 35 U.S.C. § 103 as obvious over Sauer in view of Bessler. The Examiner stated, in support of the rejection that Sauer discloses the invention substantially as claimed except for the internal endoscope, but that Bessler shows such an endoscope.

Claim 44 recites "an operating head including *a coupling structure for selectively coupling to the endoscope*, the operating head including an anvil and a stapling mechanism moveable with respect to one another between a closed position in which the anvil and the stapling mechanism are adjacent to one another and a tissue receiving position in which the anvil is separated from the stapling mechanism, *the operating head being sized so that, when in an operative position entirely located within a body lumen, structural integrity of lumenal tissue is maintained.*"

For the reasons stated above in regard to claim 36, it is respectfully submitted that neither Tsuruta nor Sauer either shows or suggests a system including "a flexible endoscope" and "an operating head including a coupling structure for selectively coupling to the endoscope, the operating head including an anvil and a stapling mechanism moveable with respect to one another between a closed position in which the anvil and the stapling mechanism are adjacent to one another and a tissue receiving position in which the anvil is separated from the stapling mechanism, the operating head being sized so that, when in an operative position entirely located within a body lumen, structural integrity of luminal tissue is maintained," as recited in claim 44.

As stated above in regard to claim 39, the rigid devices of Sauer and Tsuruta are for very different applications (i.e., open surgery) than the claimed device and these differences teach away from combinations with flexible endoscopes. Thus, none of the references provides the motivation for such a combination. Furthermore, as discussed above, combining the teaching of Bessler with any rigid device is completely contradictory to the teachings of that reference is clearly taught away from by Bessler.

Thus, it is respectfully submitted that the cited references neither show nor suggest a system as recited in claim 44 and that none of the cited references provides any motivation for the combination suggested by the Examiner.

Therefore, it is respectfully submitted that claim 44 is not rendered obvious by Tsuruta, Sauer and Bessler either taken alone or in combination and this rejection should be withdrawn. Because claims 45 - 48 depend from and include all of the limitations of claim 44, it is submitted that these claims are also allowable.

Claims 39 and 44 - 48 stand rejected under 35 U.S.C. § 103 as obvious over Sauer in view of Bessler. The Examiner stated, in support of the rejection, that Sauer shows the invention as claimed except for the use of an internal endoscope and that Bessler shows the endoscope as claimed.

As stated above in regard to the prior rejections of claims 36 and 44, Sauer shows a rigid

device unsuitable for use with a flexible endoscope and in any case inconsistent with the recitations of amended claims 36 and 44.

Specifically, it is respectfully submitted that Sauer teaches away from both “an operating capsule including *a coupling structure for selectively coupling to a flexible endoscope*, the operating capsule being sized so that, when in an operative position entirely located within a body lumen adjacent to a selected portion of tissue to be resected structural integrity of luminal tissue is maintained, the operating capsule including a suturing assembly and defining a cutting zone adjacent to the suturing assembly,” as recited in claim 36 and “an operating head including *a coupling structure for selectively coupling to the endoscope*, the operating head including an anvil and a stapling mechanism moveable with respect to one another between a closed position in which the anvil and the stapling mechanism are adjacent to one another and a tissue receiving position in which the anvil is separated from the stapling mechanism, *the operating head being sized so that, when in an operative position entirely located within a body lumen, structural integrity of luminal tissue is maintained*,” as recited in claim 44. Furthermore, it is respectfully submitted that Bessler does not cure these defects and, in any case, neither reference provides motivation for the combination.

Claims 49 - 51 stand rejected under 35 U.S.C. § 103 as obvious over Sauer in view of Kessel (DE Publication No. 4,006,673). The Examiner stated, in support of the rejection, that Sauer shows the invention as claimed with the exception of the advancing of the head over a flexible endoscope but that Kessel shows the relative sliding of a scope and forceps.

Claim 49 recites a method for resecting tissue from within a body lumen, comprising the steps of “inserting an operating head coupled to a flexible endoscope into a body lumen *via a naturally occurring body orifice*, wherein the operating head includes an anvil and a stapling mechanism” and “advancing the operating head over the endoscope within the body lumen to a desired position relative to a selected portion of tissue to be resected, wherein, *when in the desired position, the entire operating head is located within the body lumen*.”

As stated above in regard to the rejections of claims 36 and 44, it is respectfully submitted that the rigidity of the Sauer device makes it wholly unsuitable for practicing the claimed method. Specifically, whether or not the Sauer device were coupled to a flexible endoscope as suggested by the Examiner, the rigidity of the device would make it impossible to insert the device into a body lumen via a naturally occurring body orifice to a point where an operating head of the device is entirely received within the body lumen. It is respectfully submitted that Kessler suggests nothing to cure this defect and that neither reference supplies motivation to one of skill in the art to make the proposed combination.

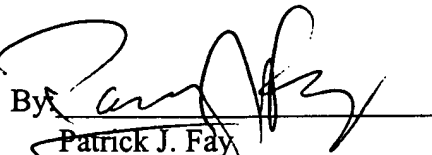
It is therefore respectfully submitted that amended claim 49 is not rendered obvious by Sauer and Kessler whether taken alone or in combination and that this rejection should be withdrawn.

Claims 36 - 51 stand rejected under the judicially created doctrine of obviousness-type double patenting over the claims of U.S. Patent Nos. 5,868,760 and 6,264,086. In view of the Terminal Disclaimer submitted herewith, it is respectfully submitted that this rejection has been obviated and should be withdrawn.

It is respectfully submitted that all of the presently pending claims are allowable and that the present application is in condition for allowance. Therefore, a prompt and favorable action on the merits is earnestly solicited. The Examiner is invited to contact the undersigned at (212) 619-6000, ext. 202 to discuss any matter concerning this application.

Respectfully submitted,

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